REMARKS

In the amendments above, Claims 20, 21, and 30 have been amended, to more particularly point out and distinctly claim Applicant's invention.

The drawings have been objected to under 37 C.F.R. § 1.83(a), and the Specification has been objected to. The Examiner's attention is directed to the amendments above, where Fig. 8 has been cancelled, Figs. 9 to 11 have been re-numbered as Figs. 8 to 10, and the Specification has been amended. It should be noted that at least a third lumen is shown in Fig. 2. Copies of Figs. 9 to 11 with the corrections in "red" are attached.

Claim 30 has been objected to, and Claims 20 and 21 have been rejected under 35 U.S.C. § 112, second paragraph. The Examiner's attention is directed to the amendments above, where the amendments are believed to overcome the bases of the objection and rejection.

Claims 20-28, 30 and 31 have been rejected under 35 U.S.C. § 102(e) as being anticipated by the Saab patent. The Examiner maintains that Saab shows a catheter (10) for intravascular corporeal cooling comprising: an elongated tubular member (12) having proximal and distal sections, an outer surface, and at least one lumen (11) extending therethrough, and annular insulation (16, 22) having proximal and distal ends arranged concentrically (Fig. 1) around the outer surface of the elongated tubular member (12) is insulated from fluid or tissue external to the annular insulation (16, 22), wherein the insulation is tapered (at 18), extends along substantially the whole length or a shorter section of the catheter (col. 16, lines 54-59) and comprises a fluid-filled member, filled with gas, water or saline (col. 9, line 66 – col. 10, line 2) and polymeric material (14, 20, col. 10, lines 38-39). The Examiner also maintains that with regard to Claim 30, the structure can be used for brain cooling.

Claims 20-24, 27 and 30-32 have been rejected under 35 U.S.C. § 102(e) as being anticipated by the Ginsburg patent. The Examiner maintains that Ginsburg shows a catheter for intravascular corporeal cooling comprising: an elongated tubular member

(20) having proximal (24) and distal (26) sections, an outer surface, and at least one lumen (28) extending therethrough, and annular insulation (18, 32, 34) having proximal and distal ends arranged concentrically (Fig. 2) around the outer surface of the elongated tubular member (20) is insulated from fluid or tissue external to the annular insulation (col. 6, lines 6-13), wherein the insulation is tapered (Fig. 11) and comprises a fluid-filled member, and at least one lumen is in communication with a source of cooled blood and/or a liquid pharmaceutical source (col. 4, lines 1-13), which can be used for brain cooling (col. 4, line 9).

Claim 29 has been rejected under 35 U.S.C. § 103(a) as being upatentable over the Ginsburg patent in view of the Donlon patent. The Examiner maintains that Ginsburg shows all of the limitations of Claim 29 except for the pressure sensor; that Donlon shows a similar catheter for placement in a blood vessel which includes a pressure sensor (38); and that it would have been obvious to one of ordinary skill in the art at the time of the invention to use a pressure sensor in the device of Ginsburg to prevent injury by which can be caused by high pressure fluids in the bloodstream.

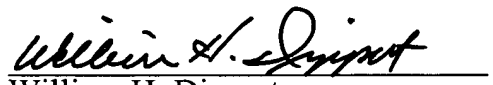
Applicant respectfully transverses the above rejections under Sections 102(a) and 103(a).

Applicant submits that whereas there may be some structural similarities, there are fundamental differences between the invention claimed here and the teachings of the cited prior art. The primary purpose of the claimed invention is to diminish heat transfer, for example, between the fluid streams, so that the inner blood stream remains relatively cool. In significant contradistinction, the prior art devices taught promote heat transfer. Systemic cooling such as taught by the cited prior art has the disadvantage than if a patient's blood temperature is lowered too much, cardiac problems may ensure.

Thus, the cited patents do not disclose or suggest Applicant's invention. Therefore, the rejections under Sections 102(b) and 103(a) should be withdrawn.

Reconsideration and allowance of the claims herein are respectfully requested. Should the claims herein be allowable but for minor matters that could be the subject of a supplemental submission or an Examiner's Amendment, Applicant would appreciate the Examiner's contacting Applicant's undersigned attorney.

Respectfully submitted,



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PORTIONS OF SPECIFICATION
MARKED UP TO SHOW CHANGES

The paragraph bridging the bottom of page 7 to the top of page 8:

According to the embodiment of the invention shown in Fig. 8, an intravascular corporeal catheter 80 comprises a longitudinal tubular member 82 that has a partially co-extensively extending inflatable insulation member 84. Insulation member 84 is sealed to the extension of tubular member 82 at distal position 86 and proximal position 88, the interior 90 of inflatable insulation member 84 being in fluid connection through inflation lumen 92 with an inflator (not shown). [inflation] Inflatable insulation member 84 is intended to have a low profile and facilitate insertion through the femoral artery 94 into the aorta 96, which is larger in diameter. Once [Inflation] inflatable insulation member 84 is positioned within aorta 96, [inflation] inflatable insulation member 84 is inflated to provide insulation when cooled blood is passed through one or more lumens 98 in catheter 82 in the direction of arrow 100.

The paragraph bridging from the bottom of page 9 to the top of page 10:

As part of the brain cooling process blood has to be removed from the patient for cooling and then returned to the patient. Preferably this can be done in a single site to minimize trauma to the patient. It is known to use a catheter set wherein an outer catheter extends only shortly distally into the patient's artery, blood is removed proximally through an annular space between the outer catheter and a distally- extending inner catheter, and cooled blood is returned through the inner catheter. However, since the available surface area for proximal blood flow is only a profile corresponding to said annular space, there are sometimes problems that develop due to pressure or fluid build-up in this area. According to an embodiment of the invention, and as shown in Fig. 10, the distal end 150 of an introducer sheath 152 contains fenestrations 154 of varied, uniform, or variable size. Cooled blood is returned in the direction represented by arrow 156, 157 through catheter 158. Body temperature blood enters introducer sheath 152 in the direction of arrows 160 at distal end 150 and through fenestrations 154, to exit at

outlet 164 in the direction of arrow 162. Fenestrations 154 preferably are circular, substantially circular, or oval, and have a diameter or effective diameter of from about 0.5 to 5 mm. It is within the scope of the invention that introducer sheath 152 comprise two concentric, slidably and/or rotably arranged tubular members so that the member and/or size of the fenestrations can be varied by rotating or sliding the outer of the two concentric members.

CLAIMS MARKED-UP
TO SHOW CHANGES

20. (AMENDED) A catheter for intravascular corporeal cooling comprising:

an elongated tubular member having proximal and distal sections, an outer surface, and at least one lumen extending therethrough, and

annular insulation having proximal and distal ends and arranged concentrically around the outer surface of the elongated external tubular member,

[whereby] wherein at least one lumen in the tubular member can provide cooled blood in the [distal] direction of the distal section of the elongated tubular member and fluid flowing through one or more lumens within the [external] tubular member is insulated from fluid or tissue external to the annular insulation.

21. (AMENDED) The catheter of Claim 20, wherein the annular insulation extends over substantially the entire [length] outer surface of the elongated tubular member.

30. (AMENDED) The catheter of Claim 20 which is adapted to be useful for brain cooling.

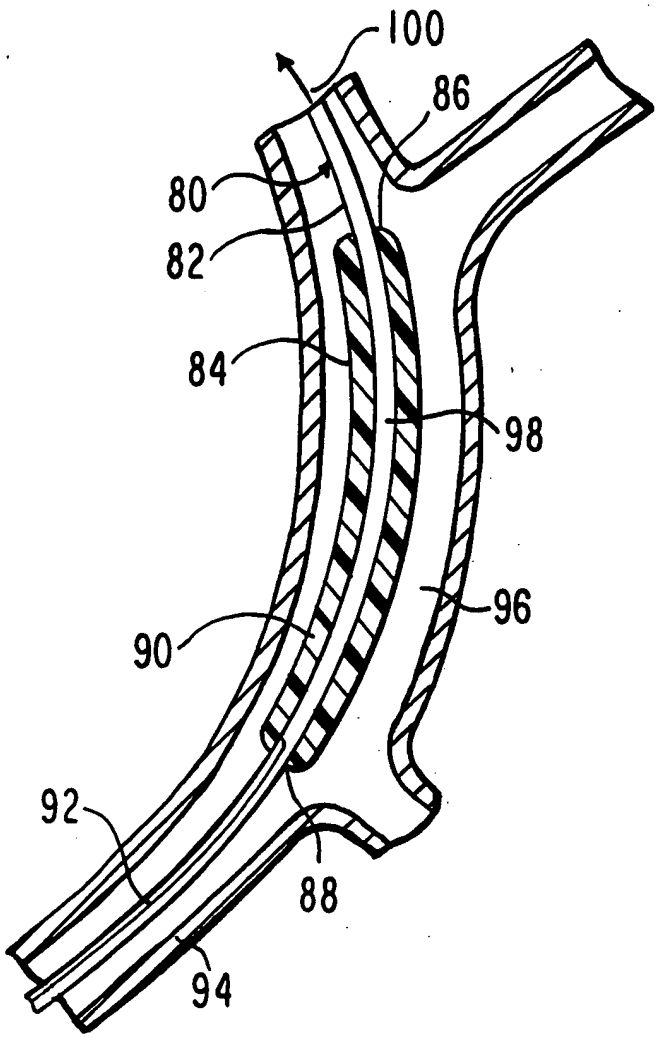

FIG. 8

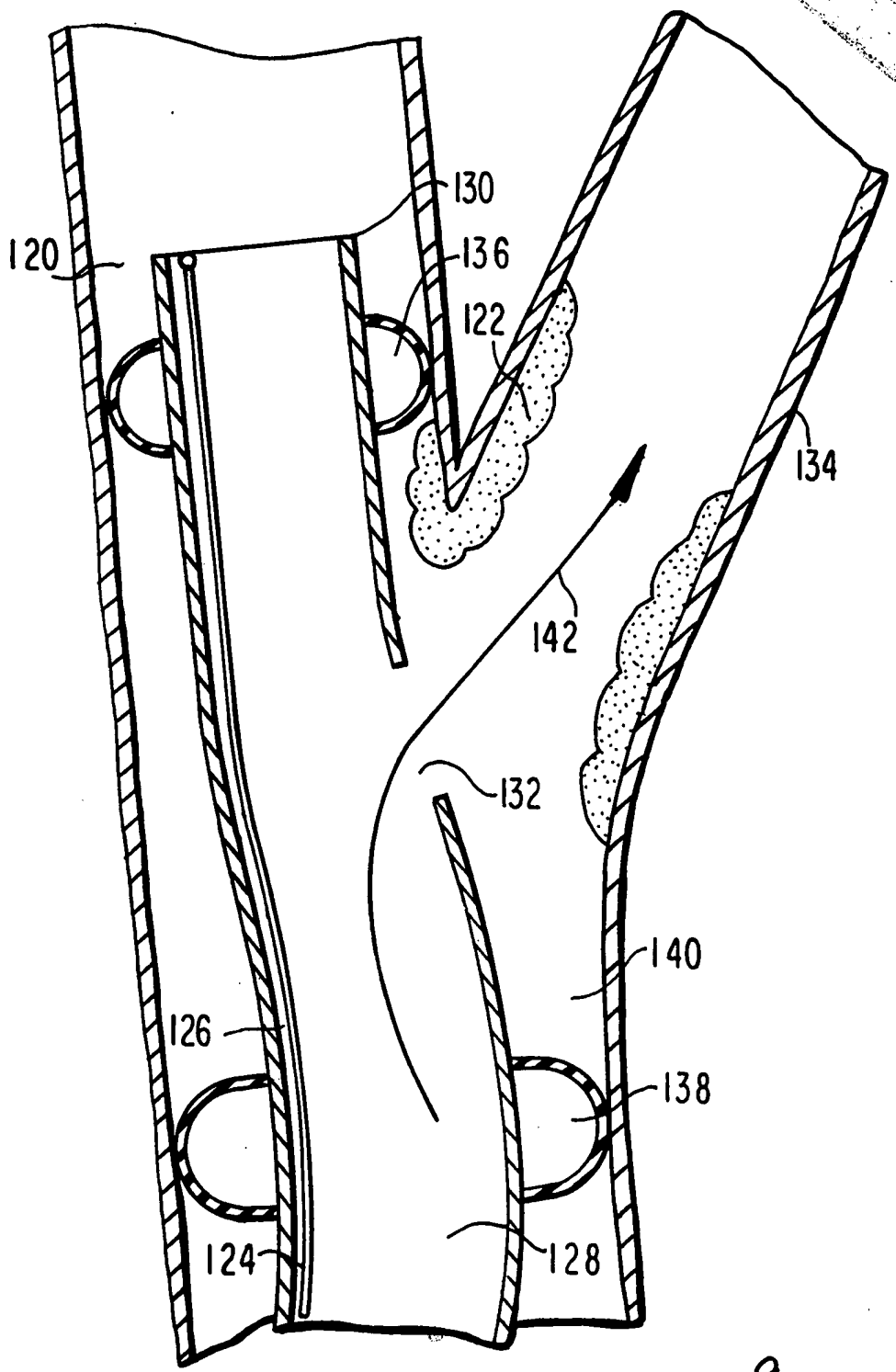

FIG. 10

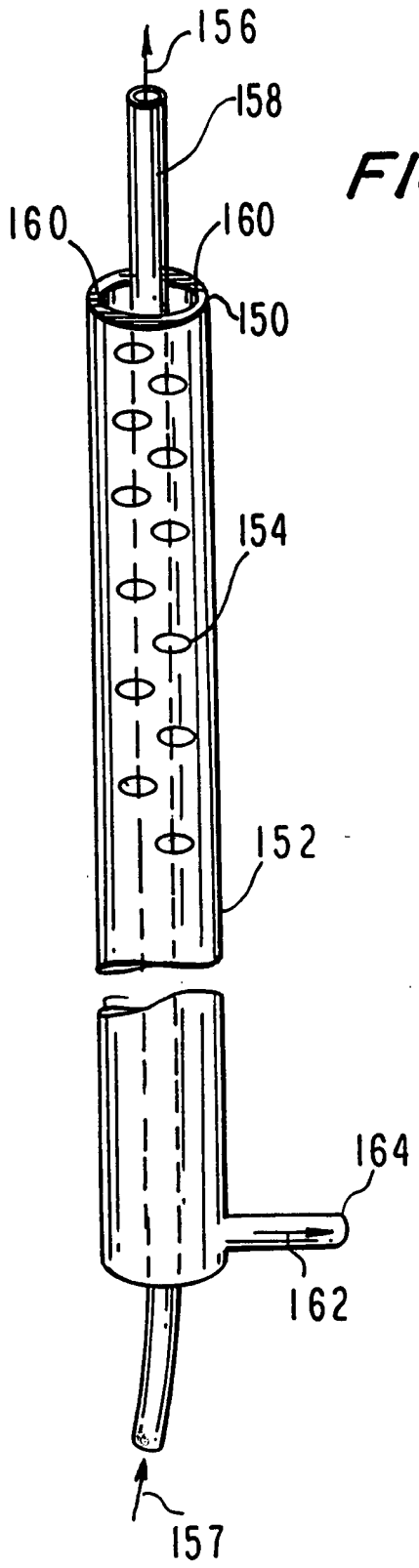

FIG. 10